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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/326,020	06/04/1999	JOHN ROBERT PORTER	CELL-0072	3600

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EXAMINER

ROBINSON, BINTA M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 08/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/326,020

Applicant(s)

PORTER ET AL.

Examiner

Binta M. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other:

D tail d Action

1. The 112 second paragraph rejection of the phrase "linker atom or group" in claims 1 and 14 at paper no. 29 is withdrawn in light of applicant's amendment at paper no. 32/C. The 112, second paragraph rejections of claims 1 and 14 at paper no. 29 are revised below. The improper Markush objection to claims 1 and 14 are withdrawn in light of applicant's amendment and remarks at paper no. 32/C. The examiner notes that while the compounds in claim 12 are allowable, claim 12 is not allowable as stated previously at paper no. 11.

(Old Rejections)

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 15 in part is rejected under 35 U.S.C. 112, first paragraph, for reasons of record at paper no. 29. The fifth Wands factor of the predictability in the art of these compounds in the various unrelated diseases, the sixth Wands factor of the amount of direction provided by the inventor in terms of the use of these compounds for the treatment of specific diseases, and seventh Wands factor of the provision of working examples of the use of these compounds in the treatment of specific diseases are not satisfied. Additionally, the eighth Wands factor of the quantity of experimentation needed to make or use the invention based on the content of the

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disclosure is not satisfied. Undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claims are enabled by the instant specification.

(Revised Rejection)

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1 and 14 in part are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 1, page 2 of the amendment 32/C, lines 5-6, the phrase "C1-6 heteroaliphatic chain containing one, two, three or four heteroatoms or heteroatom-containing groups" is indefinite. It is not clear as to whether the heteroatoms are the same or are different.

B. In claim 14, lines 10-11, page 3 of the amendment 32/C, the phrase "C1-6 aliphatic chain or C1-6 heteroaliphatic chain containing one, two, three or four heteroatoms or heteroatom-containing groups" is indefinite. It is not clear as to whether the heteroatoms are the same or are different. Which heteroatoms is the applicant claiming?

(new rejection)

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

many Claims 1, 5-11 and 14-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for Alk1 in the compound of formula (Ia) equaling C1-6 heteroaliphatic chain containing one, two, three or four heteroatoms or heteroatom-containing groups or R4 equal to C3-10 cycloaliphatic or C7-10 polycycloaliphatic groups nor does the specification enable the treatment of all diseases or disorders involving inflammation in which the extravasation of leukocytes plays a role in a mammal with these compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in *Ex parte* Foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

✓ Claim(s) 18-19 in part are rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art

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clearly would not know how to use the claimed invention. Inhibiting the binding of alpha 4 integrins is a mechanism. The disease being treated by this inhibition is not stated. The specification must contain one practical utility in currently available form. The inhibition of an enzyme must be related to a disease that needs to be improved and this disease needs to be recited. There is no reasonable assurance that these compounds will have all of the alleged properties or have the applicants supplied the supporting data. The applicant is referred to *In re Fouché* 169 USPQ 429 ccpa, 1971, MPEP 716.02 B. The applicant is referred to *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in *Ex parte Foreman* 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In *re Wands*, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In terms of the breadth of the claims, a method of treating diseases involving inflammation in which the extravasation of leukocytes plays a role in a mammal is being claimed. Alk1 of the compound of formula (1a) also encompasses a broad

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breadthC1-6 heteroaliphatic chain containing one, two, three or four heteroatoms or heteroatom-containing groups. The nature of the invention is that these compounds are useful in the treatment of disorders involving inflammation. In terms of the fifth and sixth Wands factor, the level of predictability in the art is low and the amount of direction provided by the inventor is low since the applicant does not specify the test results for each of the tests compounds. The applicant also does not test these compounds effects on actual specified diseases. In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1 and 14 in part are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 1, line 3, page 3 of the amendment 32/C, the phrase "salts, solvates, hydrates and N-oxides thereof." Is indefinite. The applicant is only claiming "A compound" which is one compound, yet this phrase implies that more than one more compound is being claimed. It is suggested that the phrase be amended to –salts, solvates, hydrates or N-oxides thereof."

B. In claim 14, line 14, page 4 of the amendment 32/C, the phrase "salts, solvates, hydrates and N-oxides thereof." Is indefinite. The applicant is only claiming "A compound" which is one compound, yet this phrase implies that more than one more compound is being claimed. It is suggested that the phrase be amended to –salts, solvates, hydrates or N-oxides thereof."

C. In claim 12, line 1, page 3 of the amendment 28/B, the phrase "salts, solvates, hydrates and N-oxides thereof." Is indefinite. The applicant is only claiming "A compound" which is one compound, yet this phrase implies that more than one more compound is being claimed. It is suggested that the phrase be amended to –salts, solvates, hydrates or N-oxides thereof."

The IDS at paper no. 4 has been considered. The references that have been crossed out will not be considered until provided to the examiner.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Alan L Rotman
ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

BMR
8/16/02